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| 10/820,486 | 04/07/2004 | Zhi-Jian Yu | 27529 | 7395 |
| 33357 | 7590 | 02/08/2008 | | |
| ADVANCED MEDICAL OPTICS, INC. 1700 E. ST. ANDREW PLACE SANTA ANA, CA 92705 | | | | |
| | | | EXAMINER BROWN, COURTNEY A | |
| | | | ART UNIT 1616 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,486

Applicant(s)

YU ET AL.

Examiner

Courtney A. Brown

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13,21-25,27-46 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,21-25,27-46 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 21/November/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Receipt of Applicant's Amendment filed on November 21, 2007 in response to the Office Action dated August 18, 2007 is acknowledged.

Information Disclosure Statement

Receipt of Information Disclosure Statement filed on November 21, 2007 is acknowledged.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application

Claim Rejection(s)- 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,5,8,10,11,21, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase "at least about" in claims when describing the amount of cetylpyridinium chloride (CPC). It is unclear to the examiner if "about" or "at least", is the intended values.

Claim Rejection(s)- 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2,4-13, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Krezanoski et al. (US 3,882,036), Zhao (US 2003/0228393), Dykens et al. (S 2003/0105167 A1), and Huth (US 2004/0120916 A1)

Applicant Claims

Applicant claims a multipurpose solution and a multi-purpose solution for contact lens care comprising an aqueous liquid medium; 0.1 ppm to about 10 ppm cetylpyridinium chloride; a second antimicrobial component that is selected from the group consisting of polyhexamethylene biguanide, a polyhexamethylene biguanide salt and polyquaternium-1; a viscosity inducing component selected from the group consisting of cellulose derivatives and mixtures thereof; a buffer component selected from the group consisting of boric acid/sodium hydroxide and boric acid/sodium borate buffers; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant; a chelating component; a tonicity component; and taurine.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

Tusè et al. teach an anti-microbial system suitable for formulations in a wide variety of ophthalmic solutions. These compositions are useful for

storing, cleaning, or disinfecting a contact lens (abstract) and are stored as aqueous solutions (column 22, 60-end to column 24, lines 50-end).

Additionally, Tusè et al. teach antimicrobial preservative components such as cetylpyridinium chloride (CPC) and PHMB (polyhexamethylene biguanide) (column 17, lines 35-41); a viscosity adjusting agent such as Cellulose derivatives and hydroxylpropyl methylcellulose (column 18, lines 46-55 and claim 58); a buffer component such as boric acid and sodium borate (column 15, 8-26); a chelating component such as EDTA (claims 10 and 11); and a tonicity component (claim 20).

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

Tusè et al. do not teach the taurine component of the composition. Additionally, Tusè et al. do not teach the amounts of cetylpyridinium chloride, the cellulosic derivatives, the viscosity inducing component, the poly (oxpropylene)-poly (oxyethylene) block copolymer, the second antimicrobial component, the tonicity component, or the chelating component .

Krezanoski et al. teach a contact lens cleaning, storing and wetting solution is for cleaning, storing and wetting flexible silicone contact lenses

comprising a poly (oxyethylene) - poly (oxypropylene) block copolymer (see abstract). Additionally, Krezanoski et al. disclose the use of cetylpyridinium chloride as germicidal agent in an amount of 0.001(10ppm) to 0.03 %(300ppm) of the overall solution (see column 6, lines 10-22).

Dykens et al., on page 5, paragraph 48 teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Krezanoski et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with

the addition of taurine and the other noted deficiencies. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè et al. Sodium chloride and potassium chloride are known tonicity agents. Thus, it is obvious to include well-known components in the known process. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Tusè with Krezanoski et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Krezanoski et al. (US 3,882,036), Zhao (US 2003/0228393), and Huth (US 2004/0120916 A1)

Applicant Claims

Applicant claims a multi-purpose contact lens disinfecting and cleaning solution comprising an aqueous liquid medium; cetylpyridinium chloride; a second microbial agent; a poly (oxpropylene)-poly (oxyethylene) block copolymer surfactant; and taurine.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

The teachings of Tusè et al. is incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

Tusè et al. does not teach the taurine component of the composition. Additionally, Tusè et al. does not disclose the amount of cetylpyridinium chloride.

Kreznoski et al. disclose a contact lens cleaning, storing and wetting solution is provided for cleaning, storing and wetting flexible silicone contact lenses comprising a poly (oxyethylene) - poly (oxypropylene) block copolymer (a non-ionic surfactant) (see abstract). Additionally, Kreznoski et al. disclose the use of cetylpyridinium chloride as germicidal agent in an amount of 0.001(10ppm) to 0.03 %(300ppm) of the overall solution (see column 6, lines 10-22).

Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al.,

Krezanoski et al., Zhao, and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted deficiencies. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Tusè with Krezanoski et al., Zhao, and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 34-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Krezanoski et al. (US 3,882,036), Zhao (US 2003/0228393), Dykens et al. (S 2003/0105167 A1), and Huth (US 2004/0120916 A1).

Applicant Claims

Applicant claims a multi-purpose solution for contact lens care comprising an aqueous liquid medium; .1ppm to about 10ppm cetylpyridinium chloride; a non-ionic surfactant; a buffer component comprising boric acid; hydroxypropylmethyl cellulose (the viscosity inducing component); EDTA(a chelating component); a combination of sodium chloride and potassium chloride (the tonicity component); a second antimicrobial component selected from the group consisting of biguanides, biguanide polymers, monomeric and polymeric quaternary ammonium compound, salts and mixtures thereof; and taurine.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

The teachings of Tusè et al. is incorporated herein by reference and are therefore applied in the instant rejection as discussed above

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

Tusè et al. does not teach the taurine component of the composition. Additionally, Tusè et al. does not disclose the amounts of cetylpyridinium chloride, the cellulosic derivatives, and amount of the viscosity inducing component, the non-ionic surfactant component, the buffer component, the second antimicrobial component, the tonicity component, or the chelating component .

Kreznoski et al. disclose a contact lens cleaning, storing and wetting solution is provided for leaning, storing and wetting flexible silicone contact lenses comprising a poly (oxyethylene) - poly (oxypropylene) block copolymer (see abstract). Additionally, Kreznoski et al. disclose the use of cetylpyridinim chloride as germicidal agent in an amount of 0.001(10ppm) to 0.03 %(300ppm) of the overall solution (see column 6, lines 10-22).

Dykens et al., on page 5 [48] teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè, Krezanoski et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted deficiencies. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Together with zinc, taurine is required for proper eye health and vision. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè. Sodium chloride and potassium chloride are known tonicity agents. Thus, it is obvious to include well-known components in the known process. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed

amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Tusè with Krezanoski et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Krezanoski et al.

Applicant Claims

Applicant claims a multi-purpose solution comprising an aqueous liquid medium; a second microbial component selected from the group consisting of polyhexamethylened biguanide, a polyhexamethylene biguanide salt and polyquaternium-1.

Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)

The teachings of Tusè are incorporated herein by reference and are therefore applied in the instant rejection as discussed above

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

Tusè et al. does not teach the amounts of cetylpyridinium chloride, Krezanoski et al. disclose a contact lens cleaning, storing and wetting solution is provided for cleaning, storing and wetting flexible silicone contact lenses comprising a poly (oxyethylene) - poly (oxypropylene) block copolymer (see abstract). Additionally, Krezanoski et al. disclose the use of cetylpyridinium chloride as germicidal agent in an amount of 0.001(10ppm) to 0.03 %(300ppm) of the overall solution (see column 6, lines 10-22).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Krezanoski et al. One would be motivated to combine these teachings because as Krezanoski et al. suggest, the amount of 0.001(10ppm) to 0.03 %(300ppm) is needed to maintain sterility of the product during use (see column 6, lines 16-21). Therefore, it would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to

form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Tusè with Krezanoski et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on November 21, 2007 have been fully considered but they are not persuasive. Applicant argues that the Office has failed to make a prima facie case of obviousness and has used hindsight reconstruction because a skilled artisan would have to select about 0.1 to about 10 ppm CPC (cetylpyridinium chloride) to combine with poly (oxypropylene)-poly (oxyethylene) block copolymers. Applicant argues that a skilled artisan would not have been led to the present claims based on the singular or combined disclosures of Tuse, Zhao, Dykens, and Huth in order to arrive at the present claims.

This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Additionally, the teachings of Tuse, Dykens et al., and Huth each deal with ophthalmic formulations while Zhao teaches an herb remedy for vision and reducing eye problems.

Applicant argues that Tuse is directed primarily to "an antimicrobial peptide that is an indolicidin and that Tuse provides no motivation to select CPC in a composition that will come in contact with the eye. This is not persuasive because Applicant claims a multi-purpose solution comprising more than one antimicrobial component (see claims 4, 9, 27, 35, and 56). Secondly, Tuse discloses, in column 17, lines 20-52, a list of bacteriostatic adjuvant or preservatives and states "that many such", but not all of the preservatives listed are eye irritants and/or toxic and, "if toxic, do not come into contact with the mouth and/or skin and/or eye." Additionally, claim 18 further limits claim 1 wherein Tuse claims a **buffer compatible with application to a mammalian eye** comprising an antimicrobial preservative selected from the a group that lists cetylpyridinium chloride.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

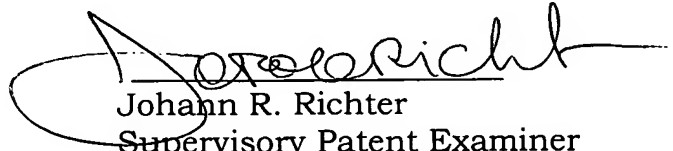
If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number or the organization where this application or proceeding is assigned is 571-273-8300.

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